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1.0 Description of the Procedure

Cytogenetics is the study of a cell's chromosomal composition by light microscopy. Cytogenetic testing involves the determination of chromosome number and structure including deletions and duplications; variations in either can produce numerous abnormalities.

Fluorescent in situ hybridization (FISH) is the application of fluorescently labeled DNA molecules to metaphase chromosomes and interphase nuclei for the detection of chromosomal abnormalities and alterations. It is a rapid, reliable, and direct approach for diagnosis, prognosis, and management of hematological malignancies. FISH is also a component of testing for some non-cancerous genetic conditions (for example, DiGeorge syndrome, William's syndrome, or Angelman syndrome) and is also used for preliminary diagnosis, prognosis, and management of pregnancies with indications for testing.

1.1 Constitutional Chromosomal Abnormalities

Constitutional chromosomal abnormalities are chromosomal abnormalities that are present at birth.

1.2 Neoplastic (Cancerous) Chromosomal Abnormalities

Cancerous chromosomal abnormalities are chromosomal abnormalities that have been acquired by a cancerous population of cells.

1.3 Genetic Counselor

Genetic counselors are health professionals with specialized education, training, and experience in medical genetics and counseling. They help people understand and adapt to the implications of genetic contributions to disease.

1.4 Genetic Counseling

Genetic counseling is a process of communication that allows patients and their families to make informed medical decisions. These services may include obtaining a structured family medical and genetic history, constructing a multiple-generation genetic pedigree, performing an analysis of available medical information for genetic risk assessment, and counseling the patient and family. This counseling includes natural history of disease, recurrence risk to family members, and availability of testing, screening and monitoring options.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid recipients may have service restrictions due to their eligibility category that would make them ineligible for this service.

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2.2 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid recipients under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination****** (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the recipient's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the recipient's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

****EPSDT and Prior Approval Requirements**

a. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***Basic Medicaid Billing Guide*:** http://www.ncdhhs.gov/dma/medbillcaguide.htm

EPSDT provider page: http://www.ncdhhs.gov/dma/EPSDTprovider.htm

3.0 When the Procedure Is Covered

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows

how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

3.1 General Criteria

Medicaid covers cytogenetic studies when they are medically necessary and

a. the procedure is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
b. the procedure can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
c. the procedure is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Medicaid covers cytogenetic studies when

a. a comprehensive history and physical examination (H&P) reveals a constellation of signs and symptoms that suggests recognizable patterns of human malformation, **or** a prenatal ultrasound reveals a structural malformation suggesting a genetic abnormality, **and**
b. the results of the studies will directly affect clinical decision making or clinical outcome for the recipient.

3.3 Constitutional Cytogenetics

Medicaid covers cytogenetic studies for constitutional chromosomal abnormalities for the diagnosis and treatment of the following conditions (this list is not all inclusive):

a. Genetic disorders (such as Down syndrome)
b. Failure of sexual development
c. Developmental delay
d. Advanced maternal age
e. Multiple malformations
f. Mental retardation

3.4 Neoplastic (Cancer) Cytogenetics

The usefulness of testing for acquired chromosomal abnormalities has been demonstrated for the diagnosis and treatment of an increasing number of cancers. Medicaid therefore covers cytogenetic studies in suspected cases of these cancers, including, but not limited to, the following:

a. Chronic myelogenous leukemia
b. Acute leukemia
c. Myelodysplasia
d. Lymphomas
e. Multiple myeloma

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3.5 Genetic Counseling

Medicaid covers appropriate genetic counseling when it is provided in conjunction with performance or consideration of medically necessary genetic studies that meet the criteria listed throughout this section. This includes follow-up genetic counseling to discuss the results of these tests. Three 30-minute units (for a total of 90 minutes) are allowed per day.

4.0 When the Procedure Is Not Covered

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

4.1 General Criteria

Cytogenetic studies are not covered when

a. the recipient does not meet the eligibility requirements listed in **Section 2.0;**
b. the recipient does not meet the medical necessity criteria listed in **Section 3.0;**
c. the procedure unnecessarily duplicates another provider's procedure; or
d. the procedure is experimental or investigational or part of a clinical trial.

4.2 Specific Criteria

Medicaid does not cover cytogenetic studies for general population screening when

a. there is no symptomatic evidence, **or**
b. the recipient does not meet the medical necessity criteria listed in **Section 3.0.**

Note: Cytogenetic studies performed primarily for family planning purposes are not covered.

5.0 Requirements for and Limitations on Coverage

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

5.1 Prior Approval

Prior approval is not required.

5.2 Provision of Service

Conventional cytogenetic testing, for routine clinical purposes, using either non-neoplastic tissue (constitutional cytogenetics) or neoplastic tissue (cancer cytogenetics), includes the following:

a. Tissue culture of the specimen
b. Metaphase arrest of dividing cells with chemicals that inhibit the mitotic spindle
c. Exposure to hypotonic solution to swell the cells and thus release the chromosomes
d. Slide preparation and staining, which permits the microscopic analysis of each chromosome in a metaphase preparation, to enable the observation of any aberrations
e. Preparation of images called karyotypes, either on paper or electronically, which display all the chromosomes of a metaphase
f. Interpretation of the results (normal or abnormal) within the context of the patient's indication for the study and clinical presentation
g. Generation of a report that conveys the patient results in cytogenetic nomenclature

5.3 Testing Limitations

a. CPT codes, 88245, 88248, 88261, 88262, 88263, 88267, 88269, 88283, 88289, and 88291 are limited to 1 unit each per day.
b. CPT codes 88230, 88233, and 88239 are limited to 2 units each per day.
c. CPT code 88271 is limited to 42 units per day.
d. CPT code 88280 is limited to 5 units per day.
e. CPT codes 88237, 88264, and 88285 are limited to 4 units each per day.
f. CPT code 88235 is limited to 3 units per conception.
g. CPT code 96040 is limited to 3 units (1 unit = 30 minutes) per day.
h. CPT codes 88272, 88273, 88274, and 88275 are limited to 25 units per day.

5.4 Documentation Requirements

Cytogenetic testing beyond the limitations stated in **Section 5.3** requires documentation supporting the need for additional test(s). Documents may include the reason for the test(s); previous lab results; and/or how the test results will be utilized, how the test results will contribute to improved health outcomes, and how the test results will alter the recipient's treatment and/or management.

6.0 Providers Eligible to Bill for the Procedure

Providers who meet Medicaid's qualifications for participation and are currently enrolled with N.C. Medicaid are eligible to bill for cytogenetic testing when it is within the scope of their practice.

Genetic counseling is provided incident to the services of a physician. Genetic counseling may be provided by board-certified or board-eligible genetic counselors employed by or under contract to hospitals or other entities that employ board-certified or board-eligible genetic or prenatal diagnostic specialists (MDs or DOs) who are also enrolled with N.C. Medicaid. The specialist must be responsible for providing on-site clinical supervision and must be directly involved in the care of recipients for whom the counseling service is billed.

Clinical laboratory services may be rendered only by medical care entities that are issued a certificate of waiver, registration certificate, or certification of accreditation under the Clinical Laboratories Improvement Amendment (CLIA)[Public Law 100-578, amended §353 of the Public Health Service Act (PHSA)].

7.0 Additional Requirements

7.1 Federal and State Requirements

Providers must comply with all applicable federal and state laws and regulations.

7.2 Hospital Inpatient Testing

Laboratories may not bill N.C. Medicaid for a test performed while a patient is in hospital inpatient status. Payment arrangements must be made between the laboratory and the hospital. Medicaid payment to the hospital includes all necessary laboratory services.

7.3 Records Retention

As a condition of participation, providers are required to keep records necessary to disclose the extent of services rendered to recipients and billed to the N. C. Medicaid program [Social Security Act 1902(a) and 42 CFR 431.107]. Records must be retained for a period of at least five years from the date of service, unless a longer retention period is required by applicable federal or state law, regulations, or agreements (10A NCAC 22F.0107).

Copies of records must be furnished upon request.

The Health Insurance Portability and Accountability Act (HIPAA) does not prohibit the release of records to Medicaid (45 CFR 164.502).

8.0 Policy Implementation/Revision Information

Original Effective Date: November 1, 1987

Revision Information:

Date	Section Revised	Change

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Attachment A: Claims-Related Information

Reimbursement requires compliance with all Medicaid guidelines, including obtaining appropriate referrals for recipients enrolled in the Medicaid managed care programs.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity. Covered ICD-9-CM diagnosis codes are listed below:

191.0	191.1	191.2	191.3	191.4	191.5	191.6	191.7
191.8	191.9	200.20	200.21	200.22	200.23	200.24	200.25
200.26	200.27	200.28	201.90	201.91	201.92	201.93	201.94
201.95	201.96	201.97	201.98	202.8	202.80	202.81	202.82
202.83	202.84	202.85	202.86	202.87	202.88	203.00	203.01
203.80	203.81	204.00	204.01	204.10	204.11	204.90	204.91
205.00	205.01	205.10	205.11	205.20	205.21	205.30	205.31
205.80	205.81	205.90	205.91	206.00	206.01	206.10	206.11
206.20	206.21	206.80	206.81	206.90	206.91	208.00	208.01
208.10	208.11	208.20	208.21	208.80	208.81	208.90	208.91
228.1	237.71	237.72	238.71	238.72	238.73	238.74	238.75
238.76	238.79	253.0	256.31	257.2	257.8	257.9	259.0
273.1	273.3	276.2	279.11	282.1	284.01	284.09	284.1
284.2	284.89	284.9	285.22	285.9	286.0	286.1	287.30
287.5	288.00	288.01	288.02	288.03	288.04	288.09	288.1
288.2	288.3	288.4	288.50	288.51	288.59	288.60	288.61
288.62	288.63	288.64	288.65	299.00	299.01	299.10	299.11
299.80	299.81	299.90	299.91	312.00	312.01	312.02	312.03
312.10	312.11	312.12	312.13	312.20	312.21	312.22	312.23
312.30	312.34	312.35	312.39	312.4	312.81	312.82	312.89
312.9	314.00	314.01	314.1	314.2	314.8	314.9	315.00
315.01	315.02	315.09	315.1	315.2	315.31	315.32	315.39
315.4	315.5	315.8	315.9	317	318.0	318.1	318.2
319	330.0	330.8	330.9	331.4	331.83	333.4	333.99
334.8	334.9	337.9	343.9	348.3	359.0	359.1	359.81
359.89	359.9	377.43	389.9	441.9	524.0	611.1	626.0
629.81	629.89	629.9	630	631	632	634.90	634.91
634.92	646.33	646.83	653.70	653.71	653.73	655.03	655.10
655.11	655.13	655.21	655.22	655.23	655.24	655.33	655.43
655.53	655.83	655.93	656.40	656.41	656.43	656.50	656.51
656.53	656.60	656.61	656.63	657.03	658.03	659.43	659.53
659.63	659.73	663.83	709.00	709.09	728.3	737.30	740.0
740.1	740.2	741.00	741.01	741.02	741.03	741.90	741.91
741.92	741.93	742.0	742.1	742.2	742.3	742.4	742.51
742.53	742.59	742.8	742.9	743.00	743.03	743.06	743.10

Codes continue on next page

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Covered ICD-9-CM diagnosis codes, continued

743.11	743.12	743.20	743.21	743.22	743.30	743.31	743.32
743.33	743.34	743.35	743.36	743.37	743.39	743.41	743.42
743.43	743.44	743.45	743.46	743.47	743.48	743.49	743.51
743.52	743.53	743.54	743.55	743.56	743.57	743.58	743.59
743.60	743.61	743.62	743.63	743.64	743.65	743.66	743.69
743.8	743.9	744.00	744.01	744.02	744.03	744.04	744.05
744.09	744.1	744.21	744.22	744.23	744.24	744.29	744.3
744.41	744.42	744.43	744.46	744.47	744.49	744.5	744.81
744.82	744.83	744.84	744.89	744.9	745.0	745.10	745.11
745.12	745.19	745.2	745.3	745.4	745.5	745.60	745.61
745.69	745.7	745.8	745.9	746.00	746.01	746.02	746.09
746.1	746.2	746.3	746.4	746.5	746.6	746.7	746.81
746.82	746.83	746.84	746.85	746.86	746.87	746.89	746.9
747.0	747.10	747.11	747.20	747.21	747.22	747.29	747.3
747.40	747.41	747.42	747.49	747.5	747.60	747.61	747.62
747.63	747.64	747.69	747.81	747.82	747.83	747.89	747.9
748.0	748.1	748.2	748.3	748.4	748.5	748.60	748.61
748.69	748.8	748.9	749.00	749.01	749.02	749.03	749.04
749.10	749.11	749.12	749.13	749.14	749.20	749.21	749.22
749.23	749.24	749.25	750.0	750.10	750.11	750.12	750.13
750.15	750.16	750.19	750.21	750.22	750.23	750.24	750.25
750.26	750.27	750.29	750.3	750.4	750.5	750.6	750.7
750.8	750.9	751.0	751.1	751.2	751.3	751.4	751.5
751.60	751.61	751.62	751.69	751.7	751.8	751.9	752.0
752.10	752.11	752.19	752.2	752.3	752.40	752.41	752.42
752.49	752.51	752.52	752.61	752.62	752.63	752.64	752.65
752.69	752.7	752.81	752.89	752.9	753.0	753.10	753.11
753.12	753.13	753.14	753.15	753.16	753.17	753.19	753.20
753.21	753.22	753.23	753.29	753.3	753.4	753.5	753.6
753.7	753.8	753.9	754.0	754.1	754.2	754.30	754.31
754.32	754.33	754.35	754.40	754.41	754.42	754.43	754.44
754.50	754.51	754.52	754.53	754.59	754.60	754.61	754.62
754.69	754.70	754.71	754.79	754.81	754.82	754.89	755.00
755.01	755.02	755.10	755.11	755.12	755.13	755.14	755.20
755.21	755.22	755.23	755.24	755.25	755.26	755.27	755.28
755.29	755.30	755.31	755.32	755.33	755.34	755.35	755.36
755.37	755.38	755.39	755.4	755.50	755.51	755.52	755.53
755.54	755.55	755.56	755.57	755.58	755.59	755.60	755.61
755.62	755.63	755.64	755.65	755.66	755.67	755.69	755.8
755.9	756.0	756.10	756.11	756.12	756.13	756.14	756.15
756.16	756.17	756.19	756.2	756.3	756.4	756.50	756.51
756.52	756.53	756.54	756.55	756.56	756.59	756.6	756.70
756.71	756.79	756.81	756.82	756.89	756.9	757.0	757.1
757.2	757.31	757.32	757.33	757.39	757.4	757.5	757.6
757.8	757.9	758.0	758.1	758.2	758.3	758.31	758.32
758.33	758.39	758.4	758.5	758.6	758.7	758.81	758.89
758.9	759.0	759.1	759.2	759.3	759.4	759.5	759.6

Codes continue on next page

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Covered ICD-9-CM diagnosis codes, continued

759.7	759.81	759.82	759.83	759.89	759.9	760.71	778.0
779.8	779.9	780.39	783.1	783.40	783.41	783.42	783.43
796.4	796.5	796.6	996.85	996.89	V16.0	V16.3	V16.41
V42.81	V42.82						

C. Procedure Code(s)

CPT Code	Description
88230	Tissue culture for non-neoplastic disorders; lymphocyte
88233	Tissue culture for non-neoplastic disorders; skin or other solid tissue biopsy
88235	Tissue culture for non-neoplastic disorders; amniotic fluid or chorionic villus cells
88237	Tissue culture for neoplastic disorders; bone marrow, blood cells
88239	Tissue culture for non-neoplastic disorders; solid tumor
88245	Chromosome analysis for breakage syndromes; baseline Sister Chromatid Exchange (SCE), 20–25 cells
88248	Chromosome analysis for breakage syndromes; baseline breakage, score 50–100 cells, count 20 cells, 2 karyotypes (eg, for ataxia telangiectasia, Fanconi anemia, fragile X)
88261	Chromosome analysis; count 5 cells, 1 karyotype, with banding
88262	Chromosome analysis; count 15–20 cells, 2 karyotypes with banding
88263	Chromosome analysis; count 45 cells for mosaicism, 2 karyotypes with banding
88264	Chromosome analysis; analyze 20–25 cells
88267	Chromosome analysis, amniotic fluid or chorionic villus, count 15 cells, 1 karyotype, with banding
88269	Chromosome analysis, in situ for amniotic fluid cells, count cells from 6–12 colonies, 1 karyotype, with banding
88271	Molecular cytogenetics; DNA probe, each (eg, FISH)
88272	Molecular cytogenetics; chromosomal in situ hybridization, analyze 3–5 cells (eg, for derivatives and markers)
88273	Molecular cytogenetics; chromosomal in situ hybridization, analyze 10–30 cells (eg, for microdeletions)
88274	Molecular cytogenetics; interphase in situ hybridization, analyze 25–99 cells
88275	Molecular cytogenetics; interphase in situ hybridization, analyze 100–300 cells
88280	Chromosome analysis; additional karyotypes, each study
88283	Chromosome analysis; additional specialized banding technique (eg, NOR, C-banding)
88285	Chromosome analysis; additional cells counted, each study
88289	Chromosome analysis; additional high resolution study
88291	Cytogenetics and molecular cytogenetics, interpretation and report
96040	Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family

D. Modifiers

Providers are required to follow applicable modifier guidelines. Genetic testing code modifiers listed in the Current Procedural Terminology (CPT 2008 codebook) are excluded from this policy.

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E. Billing Information

Please refer to **Section 5.3 Testing Limitations,** for Medicaid billing.

For genetic counseling, CPT code 96040 is limited to 3 units (1½ hours) per day. (1 unit = 30 minutes.)

For diagnostic testing for claims purposes, the date of service of the test shall be the date the specimen was collected.

F. Place of Service

Inpatient, outpatient, clinic

G. Co-Payments

Laboratory services are not subject to co-payments.

H. Reimbursement

Providers must bill their usual and customary charges.